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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,025	02/19/2002	Villoo Morawala Patell	145865.00005	5370

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Sidley Austin Brown & Wood LLP
1501 K Street N W
Washington, DC 20005

EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/868,025	Applicant(s) PATELL ET AL.	
	Examiner Medina A Ibrahim	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/16/05.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,10 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 10-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's response filed 12/16/04 in reply to the Office action of 08/16/04 has been entered. Claims 6-8 have been cancelled. Claims 1-2 and 10-11 have been amended. Claims 1-2, 10 and 11 are pending and are examined.

All previous objections and rejections not set forth below have been withdrawn in view of Applicant's amendment to the claims. Upon further search and consideration, it has determined that the indicated allowability of claims 1-2 and 10-11 be withdrawn. This Office action contains NEW GROUNDS OF REJECTIONS not necessitated by Applicant's amendments. Therefore, this action is non-final. The delay in applying these grounds of rejection is regretted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The claims are directed to an isolated nucleic acid comprising the polynucleotide sequence of SEQ ID NO: 1 encoding SEQ ID NO: 2, a transgenic plant comprising a recombinant expression cassette comprising a plant promoter operably linked to said polynucleotide sequence, and a method of conferring salt tolerance on a plant by transforming the plant with said recombinant expression cassette.

Applicant teaches identification and isolation of the polynucleotide sequence of SEQ ID NO: 1 encoding SEQ ID NO: 2 from the rice variety IR-64 (pages 10-11). Applicant also teaches a construct comprising said polynucleotide transformed to M15 cells for expression of the polypeptide (pages 12). On page 9, the last two full paragraphs, Applicant states IR64 is a salt stress susceptible variety. On page 13 of the specification, it is indicated that no similar gene and protein sequence or with similar pattern of the disclosed sequences could be found in the protein/gene databases.

Applicant asserts that the polynucleotide sequence of SEQ ID NO: 1 encoding SEQ ID NO: 2 can be used to induce salt stress tolerance in transgenic plants. Applicant assertion is based solely because this gene was found to be overexpressed in IR-64 stressed plants as compared to the IR-64 control plants. However, based upon Applicant's disclosure, one skilled in the art would ascertain that the disclosed polynucleotide would have salt or any other abiotic stress tolerance activity in a transgenic plant for the following reasons: 1) the structure and function of SEQ ID NO: 1 encoding SEQ ID NO: 2 was predicted using computational biology (see page 14, the last two full paragraphs). 2) A prior art search didn't reveal any similar sequence implicated in salt or other abiotic stress tolerance. 3) The rice variety IR-64 from which

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SEQ ID NO: 1 has been isolated is a salt stress susceptible variety. 3) No functional domains for stress tolerance or any other biological function has been disclosed for SEQ ID NO: 1 and 2; and 4) no transgenic plant with increased tolerance to salt stress as a result of overexpressing SEQ ID NO: 1 or 2 has been disclosed.

The state of the prior art as evidenced by Applicant's specification indicates that salt stress tolerance is a complex mechanism involving several factors including severity and duration of the stress, the plant genotype/variety, developmental stage and the organ exposed to the stress (page 7 of the specification). The specification further states that salt stress induces the expression of several genes having either a regulatory role in gene expression or functional role in plant's response (page 8 of the specification). It is unclear what role SEQ ID NO: 1 or 2 might have in stress tolerance, if any. Therefore, it is apparent that further research not considered to be routine would be required before one skilled in the art would know the function and thus how to use Applicants' SEQ ID NO: 1 encoding SEQ ID NO: 2 to enhance an agronomic trait in a transgenic plant. The specification provides no more than an invitation to experiment requiring undue trial and error experimentation.

In *Genentech Inc v. Novo Nordisk A/S* (42 USPQ2d 1001 at p. 1005) the court stated "(p)atent protection is granted in return for an enabling disclosure of an invention, not for vague intiminations of general ideas that may or may not workable.... . When there is no disclosure of. ...or of any of the conditions under which a process can be carried out, undue experimentation is required....". Applicant is here expecting others to determine how to use the disclosed sequences in a transgenic plant to increase/induce

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a desired agronomic trait, if any.

Applicant is invited to provide evidence in the form of data or declaration under 1.132 to support the stress tolerance activity of SEQ ID NO: 1 in a transgenic plant.

Remarks

Claims 1-2 and 10-11 are deemed free of the prior art of record because the prior art does not teach or reasonably suggest SEQ ID NO: 1 or a nucleotide sequence encoding SEQ ID NO: 1.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mai

3/6/05

MEDINA A. IBRAHIM
PATENT EXAMINER

